Reference number(s)
2787-A

SPECIALTY GUIDELINE MANAGEMENT

LORBRENA (lorlatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Lorbrena is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on:
- Crizotinib and at least one other ALK inhibitor for metastatic disease; or
- Alectinib as the first ALK inhibitor therapy for metastatic disease; or
- Ceritinib as the first ALK inhibitor therapy for metastatic disease

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

B. Compendial Uses
Single-agent therapy for recurrent, advanced or metastatic NSCLC in patients with:
1. ALK rearrangement-positive tumors
2. ROS1 rearrangement-positive tumors, following disease progression on crizotinib, entrectinib or ceritinib

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart documentation indicating ALK mutation status or ROS1 rearrangement status as applicable to Section III.

III. CRITERIA FOR INITIAL APPROVAL

Non-small cell lung cancer (NSCLC)

A. Authorization of 12 months may be granted for treatment of ALK rearrangement-positive recurrent, advanced or metastatic NSCLC as a single-agent.

B. Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic NSCLC as a single-agent therapy when all of the following criteria are met:
1. The disease is ROS1 rearrangement-positive
2. The disease has progressed on any of the following: ceritinib, crizotinib, or entrectinib.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity while on the current regimen.

V. REFERENCES

1. Lorbrena [package insert]. New York, NY: Pfizer, Inc.; May 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 17, 2020.